

## Remarks

The Examiner is correct in remarking that US Patent Application 09/297,189 has been a patent since July 3, 2001 (US Patent 6,254,855 B1). We apologize for having missed giving reference to this patent in preparation of our response to the Office Action mailed June 21, 2001.

However, we respectfully do not agree with the statement that '855 discloses subject matter that is the same as in the present Patent Application. The cited document does not determine the thickness of the particles at all (see column 2, lines 20 to 23 of '855 in comparison to page 2, lines 26 to 31 of the present application).

Therefore, we regard the present application as disclosing new and inventive subject matter and we respectfully believe that there is no need to file a terminal disclaimer.

As a consequence of the discussion above, '855 does not present double-patenting.

Furthermore, the Examiner is of the opinion that the specification does not disclose particles being characterized as anisotropically shaped as expressed in the remarks concerning the first Office Action.

The term "anisotropically shaped" was used to describe the particles with dimensions that differ in length, width and thickness. That means having different properties in size in each direction. The particles are of rectangular cross section and have an extremely small thickness of only 5 nm ( $0.005\text{ }\mu\text{m}$ , i.e.,  $5.10^{-9}\text{ m}$ ; see page 2, lines 26 to 31). We now realize that there is a misunderstanding of the term "anisotropically shaped".

However, we respectfully do not share the Examiner's point of view regarding the property of the particles' shape as not being disclosed. In fact, the specification of the present Patent Application describes the geometry of the particles in detail. Thus, despite that the use of

the term “anisotropic” in the argumentation given in the reply to the first Office Action may have been misunderstood, the argumentation as such is valid concerning the topics discussed.

They newly cited documents (Ichitsuka et al (I) and (II) relate to a process for producing shaped articles of oriented calcium phosphate and sinters thereof. These documents do not comprise any disclosure of a stomatic composition as given in the present Patent Application. In addition, as the Examiner himself notes in the Office Action, the documents do not anticipate, describe or disclose an embodiment of the product of HAP particles of the length, width, and height claimed in the present application and provide no guidance on how to make them.

To the contrary, the present invention relates to a stomatic composition which is disclosed in detail in the specification. In particular, the invention does not relate to a method for preparing anisotropic HAP-particles. Thus, the feature of how to prepare the particles is not an issue of the present Patent Application.

HA's property of being useful as biomaterial which is osteo-reparative and, in particular, its application in the field of stomatology is commonly known, as is cited in the prior art section of the present application, as well as in the newly cited documents (Ichitsuka (I), col. 2, lines 9-10; and Ichitsuka (II), col. 1, lines 11 to 13). The disclosure of the present Patent Application is not the use of HAP as such, but rather, providing a stomatic composition including HAP particles of determined dimensions in length, width and thickness.

The European Patent Application EP 664133 (Rubin et al.) discloses a method for producing a preparation for stimulating growth in bone tissue in common. The particular scope of this invention is reconstructive bone surgery, which of course includes surgical stomatology, besides traumatology and orthopeadics. (Compare the first sentence of the Abstract of the Disclosure).

However, the present Patent Application relates specifically to a product for stomatic applications as indicated by the title “stomatic composition”. The disclosure of the present application comprises in detail the best mode contemplated by the inventor concerning how to prepare the stomatic composition (see page 2, lines 26 to 31; page 3, line 29 to page 5, line 21, examples 1 to 9).

Thus, the disclosures of Rubin, ‘855, Ichitsuka (I) and Ichitsuka (II) do not anticipate the use of a stomatic composition including the particles shaped and sized in the new and inventive way discussed above.

Valid rejection under 35 USC 102 requires that each feature of the rejected claims be disclosed in a single reference. None of the cited patents disclose each of features of the rejected claims 1 to 8 or 10.

In order to make the importance of the particle dimensions, especially of the extremely small thickness of only 5 nm even more clear to overcome the Examiner’s remaining objections, the feature of a specific surface of 100 to 1510 m<sup>2</sup>/g as claimed in claim 4 is included in claim 1, in addition to the exact determination of the complete dimensions, which are already given.

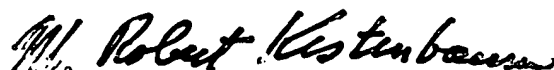
Claim 1 is amended to include the feature of the specific surface as disclosed in claim 4. Consequently, claim 4 is deleted. Amended claim 1 now recites:

“A composition for stomatic applications characterized in that it comprises particles of hydroxyapatite with an average particle size in length (l), width (d) and thickness (h) of: 1 from 0.2 μm to 0.01 μm, d from 0.1 μm to 0.0001 μm, and h from 0.1 μm to 0.0001 μm with the particles of hydroxyapatite having a specific surface of hydroxyapatite from 100 m<sup>2</sup>/g to 150 m<sup>2</sup>/g.

A three-month extension of time in which to response to the outstanding Office Action is hereby requested. PTO-2038 authorizing credit card payment for the amount of \$460 is enclosed for the prescribed Small Entity three-month extension fee. Any other fee due by virtue of this filing or this application should be charged to Deposit Account 11-0665. Any refunds in connection with this filing should be credited to Deposit Account 11-0665. A duplicate of this page is enclosed for this purpose.

Wherefore, further consideration and allowance of the claims in this application is respectfully requested.

Respectfully submitted,



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I hereby certify this correspondence is being deposited with the U.S Postal Service as a first class mail in an envelope with adequate postage addresses to Commissioner for Patents, Washington, D.C. 20231 on May 1, 2002.



M. Robert Kestenbaum

**"Version with Markings to show Changes Made"**

1. (Amended twice) A stomatic composition characterised in that it comprises particles of hydroxyapatite with an average particle size in length (l), width (d) and thickness (h) of:  
(l) from about 0.2  $\mu\text{m}$  to about 0.01  $\mu\text{m}$ , (d) from about 0.1  $\mu\text{m}$  [tp] to 0.001, and (h) from about 0.1  $\mu\text{m}$  to about 0.0001 [1]  $\mu\text{m}$ .
2. (Amended twice) The stomatic composition according to claim 1 characterised in that it comprises particles of hydroxyapatite with an average particle size in length (l), width (d) and thickness (h) of about (l) = 0.06  $\mu\text{m}$  +/- 50%, (d) = 0.015  $\mu\text{m}$  +/- 50% and (h) = 0.005  $\mu\text{m}$  +/- 50%.
3. (Amended twice) The stomatic composition according to claim 1 characterised in that it comprises particles of hydroxyapatite with an average particle size in length (l), width (d) and thickness (h) of about (l) = 0.06  $\mu\text{m}$ , (d) = 0.015  $\mu\text{m}$ , (h) = 0.005  $\mu\text{m}$ .  
Please cancel claim 4.
5. The stomatic composition according to claim 1 characterized in that it comprises said hydroxyapatite particles ultra finely divided.
6. The composition according to claim 1 characterised in that the ultra finely divided hydroxyapatite particles are present in the composition in an amount of 0.1% to 50% by weight.
7. The composition according to claim 1 characterised in that the ultra finely, divided hydroxyapatite is a synthetic hydroxyapatite which contains 99.9% of  $\text{Ca}_{10}(\text{PQ}_4)_6(\text{OH})_2$  by weight.
8. The composition according to claim 1 further characterised by at least one substance of the group consisting of

- humectants in a range from about 0% to 85% by weight,
  - bindings and thickeners in a range of 0% to 10% by weight,
  - abrasive materials in a range from 0.0% to 25%,
  - Surfactants in a range from 0% to 5% by weight,
  - Flavours in a range from 0% to 5% by weight.
9. The composition according to claim 1 further characterised by agents enhancing the gingivitis system of the mouth cavity and comprising extracts of natural plants including at least one of the group consisting of urtica, millefolium, chamomilla hypericum, salvia, etc. in the aqueous and in the aqueous-alcoholic form.
10. The composition according to claim 1 further characterised by effective amounts of anti-microbial and anti-plaque agents.
11. (Amended) A stomatic composition comprising particles of hydroxyapatite with an average particle size in length (l), width (d) and thickness (h) of: (l) from about 0.2  $\mu\text{m}$  to about 0.01  $\mu\text{m}$ , (d) from about 0.1  $\mu\text{m}$  to about 0.001  $\mu\text{m}$ , and (h) from about 0.1  $\mu\text{m}$  to about 0.0001  $\mu\text{m}$ , and effective amounts of gingivitis systems of the mouth cavity comprising extracts of natural plants including at least one of the group consisting of urtica, millefolium, chamomilla hypericum, and salvia, in an aqueous or an aqueous-alcoholic form.